

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

**IN RE: DIGITEK    PRODUCT    LIABILITY  
LITIGATION**

**MDL NO. 1968**

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**THIS DOCUMENT RELATES TO ALL CASES**

**MYLAN DEFENDANTS' REPLY MEMORANDUM IN SUPPORT OF THE  
MOTION TO DISMISS COUNTS ONE, TWO AND THREE OF THE  
MASTER CONSOLIDATED COMPLAINT FOR INDIVIDUALS**

**I.        INTRODUCTION**

Plaintiffs' Response in Opposition to Mylan Defendants Motion to Dismiss Counts One, Two, and Three of the Master Consolidated Complaint for Individuals fails to rebut the arguments advanced by Mylan Defendants in support of dismissal. Plaintiffs' reliance on *Conley's* "no set of facts" pleading standard is misplaced; current United States Supreme Court case law requires Plaintiffs to plead enough facts to establish a plausible claim for relief against Mylan Defendants. Plaintiffs failure to do so requires dismissal under Rule 12(b)(6). Counts Two (Manufacturing Defect) and Three (Design Defect) should be dismissed in cases originating in jurisdictions that exempt non-manufacturing sellers from liability for manufacturing and design defects.

**II.       ARGUMENT**

**A.       Plaintiffs' Opposition to Dismissal of Count One Demonstrates a Fundamental Misunderstanding of the Proper Pleading Standard Under Rule 8.**

Plaintiffs rely on the "no set of facts" standard enunciated in *Conley v. Gibson* in 1957 to support their contention they are not required to set forth facts supporting the elements of their failure-to-warn claim against Mylan Defendants. *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). *Conley*, however, is not the proper standard for pleading under Federal Rule of Civil Procedure

8. The United States Supreme Court expressly denounced *Conley's* “no set of facts” standard in 2007, noting that a literal reading of this language would allow “a wholly conclusory statement of claim [to] survive a motion to dismiss whenever the pleadings left open the possibility that a plaintiff might later establish some ‘set of [undisclosed] facts’ to support recovery.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 561 (2007). *Twombly* makes it clear that to survive a motion to dismiss under Rule 12(b)(6), the complaint must assert enough facts to support a claim that is *plausible*—as opposed to merely possible—on its face. *Id.* at 547.

Plaintiffs fail to allege any facts that plausibly establish Mylan Defendants, as distributors, knew or had reason to know of a manufacturing defect in Digitek® prior to Actavis Totowa LLC’s (“Actavis”) decision to recall the product. Plaintiffs base their claim against Mylan Defendants on the wholly conclusory assertion that FDA communications to Actavis regarding deficiencies at its Little Falls facility were *de facto* communications to all defendants. Master Complaint at ¶¶ 19, 21, 23, 24, 37. The Master Complaint is devoid of independent factual allegations regarding Mylan Defendants’ knowledge of a manufacturing defect<sup>1</sup> and the documents cited by Plaintiffs in support of their claim clearly show that Mylan Defendants were neither parties to nor intended recipients of FDA communications to Actavis. An unsupported conclusory allegation of knowledge, without more, is not sufficient to establish a plausible claim to relief against Mylan Defendants for failure to warn. *Bass v. E.I. DuPont Nemours & Co.*, 324 F.3d 761, 765-66 (4<sup>th</sup> Cir. 2003); *Twombly*, 550 U.S. at 556-57, 561-62.

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<sup>1</sup> For instance, the Master Complaint does not allege that Mylan Defendants had access to FDA communications directed solely to Actavis, that FDA communicated directly with Mylan Defendants regarding deficiencies observed at Actavis’ Little Falls’ facility, or that Mylan Defendants became aware of this information prior to Actavis’ decision to recall Digitek®.

**II. Counts Two (Manufacturing Defect) and Three (Design Defect) Should Be Dismissed in Cases Originating in Jurisdictions Exempting Sellers from Liability for Defective Products.**

Plaintiffs cite case law from four jurisdictions in support of their claim that the majority of jurisdictions do not exempt distributors from liability for manufacture and design defects. Of the four jurisdictions cited by Plaintiffs, only three—Arizona, New York and West Virginia—hold distributors liable for defective products. Contrary to Plaintiffs’ assertion, Texas generally exempts non-manufacturing sellers of defective products from liability for design and manufacturing defects. TEX. CIV. PRAC. & REM. CODE ANN. § 82.003 (Vernon 2005).


Mylan Defendants are entitled to dismissal for cases that originated in jurisdictions that exempt distributors from liability for manufacture and design defects.

**IV. PRAYER**

For the reasons stated above as well as those set forth in the Memorandum in Support of Mylan Defendants’ Motion to Dismiss Counts One, Two, and Three of the Master Consolidated Complaint for Individuals, Mylan Defendants respectfully request that this Court dismiss with prejudice Counts One, Two and Three of the Master Complaint and grant such other relief as the Court may deem just and proper.

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IN RE: DIGITEK PRODUCT LIABILITY  
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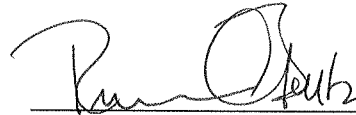
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CERTIFICATE OF SERVICE

I hereby certify that on June 2, 2009, I electronically filed the foregoing "Mylan Defendants' Reply Memorandum in Support of the Motion to Dismiss Counts One, Two and Three of the Master Consolidated Complaint for Individuals" with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.



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